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New Federal Regulations for Improving Quality in Opioid Treatment Programs

Luc R. Pelletier, MSN RN CS CPHQ and

Luc R. Pelletier is a healthcare consultant in Washington, DC, and is Editor-in-Chief of JHQ. When he wrote this article, he was project director for the Performance Measurement for Treatment Improvement (PMTI) project at Danya International, Inc., in Silver Spring, MD. In October 2001, Pelletier was the recipient of the American Psychiatric Nurses Association Excellence in Leadership Award–Advanced.

Jeffrey A. Hoffman, PhD

Jeffrey A. Hoffman is president and chief executive officer of Danya International, Inc. Dr. Hoffman served as principal investigator for the PMTI project.

Abstract

The U.S. Food and Drug Administration (FDA) has enforced federal requirements related to the use of methadone since 1972; regulations essentially have not changed for nearly 30 years. With Congress' recently released federal regulations for opioid treatment programs (OTPs), however, oversight of OTPs has shifted from the FDA to the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA's Center for Substance Abuse Treatment developed guidelines for accreditation agencies such as the Joint Commission on Accreditation of Healthcare Organizations and The Rehabilitation Accreditation Commission...CARF to develop standards for OTPs. Preliminary findings show that OTPs are indeed able to meet these accreditation standards. This article reviews the need for the changes, the history of methadone treatment oversight, the development of accreditation requirements, stakeholders' initial response to the proposed regulations, and performance domains of importance to OTPs.

Keywords

accreditation; CARF; JCAHO; program evaluation; quality improvement

In January 2001, Congress released new federal regulations that reflect the collaboration of the U.S. Department of Health and Human Services (DHHS), the White House Office of National Drug Control Policy (ONDCP), and the U.S. Department of Justice to improve quality and clinical outcomes of methadone treatment programs. ONDCP estimates that "there are 980,000 heroin addicts in the United States," with "roughly 20 percent [196,000] receiving methadone or levo-alpha-acetyl-methadol (LAAM) as part of an addiction treatment program" (Substance Abuse and Mental Health Services Administration [SAMHSA], 2001). The regulations do not include standards permitting physicians to prescribe methadone and LAAM in office-based practices that are not affiliated with opioid treatment programs (OTPs). Under the new regulations, oversight of methadone treatment programs has shifted from the Food and Drug Administration's (FDA) inspection model to a SAMHSA-administered accreditation model.

A Need for Significant Change

Why is there a need for comprehensive quality management (QM) systems for methadone treatment programs? By the end of the 20th century, evidence of shortfalls in the general American healthcare system was beginning to be reported to large consumer audiences, and, in fact, there long has been a sense that healthcare in the United States is in serious trouble. A study in Colorado and Utah revealed that adverse events accounted for high healthcare costs. Total healthcare costs that were the result of adverse events accounted for \$661,889,000; for preventable adverse events, the costs were \$308,382,000 for these two states (in 1996 dollars). If one extrapolates these findings to the 33 million inpatient admissions in the United States in 1996, total costs were estimated to be \$37.6 billion for adverse events and \$17 billion for preventable adverse events (Thomas et al., 1999). In New York in 1984 the number of adverse events associated with medical error was 98,609; 13.6% of these adverse events led to death (Brennan et al., 1991). It is estimated that medical errors are responsible for more deaths in the United States than traffic accidents, breast cancer, or AIDS (Committee on Quality of Health Care in America, 2000).

Although these statistics relate primarily to medical problems, quality problems in the diagnosis and treatment of addictive disorders, including opioid dependence, likely exist. Findings and analysis from a standardized quality measurement and management strategy, used by a significant number of methadone treatment programs throughout the U.S., could confirm or refute the supposition that there are quality problems in this subpopulation. The concern about healthcare quality and the lack of standardized opioid-specific performance measures led to the development of federal regulations to guide OTPs in developing and continuously refining their treatment strategies and to help them move toward an accreditation model.

From Regulation to Accreditation: A Move Toward Accountability and Quality

In 1990, the U.S. General Accounting Office (GAO) reported that both high- and low-quality methadone treatment programs could meet regulatory requirements, a finding that suggested that the existing FDA regulations for methadone programs did not ensure quality treatment (GAO, 1990). GAO also expressed concern that the oversight of methadone treatment was oriented primarily toward ensuring that programs met minimum regulatory requirements for proper record-keeping and service provision. The GAO recommended that results-oriented performance standards be developed for methadone programs to improve the quality of treatment. Similarly, a 1995 Institute of Medicine (IOM) report identified a need for more reliance on best practice standards and physician discretion in the assessment of opioid addiction treatment (Committee on Federal Regulations of Methadone Treatment, 1995).

Growing concern about the need to monitor and improve the effectiveness of opioid addiction treatment programs led to the design and testing, with funding from the National Institute on Drug Abuse (NIDA), of the Methadone Treatment Quality Assurance System (MTQAS), an outcomes-focused performance measurement system (Phillips et al., 1995). There also has been movement toward an accreditation/regulatory model for opioid addiction treatment, which emphasizes quality of care and focuses on results as well as on process. In a recent initiative funded by SAMHSA's Center for Substance Abuse Treatment (CSAT), The Rehabilitation Accreditation Commission (CARF) and the Joint Commission on the Accreditation of Healthcare Organizations have each developed standards for opioid addiction treatment and have implemented field-testing of these standards (CSAT, 1999c).

For the most part, quality management/quality improvement (QM/QI) activities have played a limited role in opioid addiction treatment programs. A key reason for this is that accreditation, a major impetus for formalized QM/QI, had not been as widely employed by substance abuse treatment programs as it has by other healthcare facilities and programs (Lohr, Schlenger, & Luckey, 1998). The development of accreditation standards for opioid addiction treatment and the fact that an accreditation/regulatory model has recently replaced the former regulatory model will increase the need and motivation for opioid addiction treatment programs to initiate QM/QI activities. Performance measurement initiatives will be a necessary component of a comprehensive QM/QI strategy.

With the exception of MTQAS, however, a thorough review of the literature has not identified any performance measurement system for QM/QI designed specifically for OTPs. Furthermore, while MTQAS clearly includes key outcome indicators for OTPs, it was developed before the recently drafted accreditation standards for OTPs. In addition, final results of the MTQAS feasibility test indicate that OTPs may have had difficulty interpreting MTQAS data and translating the findings into concrete performance improvement action plans (CSAT, 1999b).

The “CSAT Guidelines for the Accreditation of Opioid Treatment Programs” (CSAT, 1999a) formed the basis for the standards developed by the Joint Commission and CARF and are described briefly here.

CSAT Accreditation Guidelines

The CSAT guidelines were developed to guide accreditation agencies in developing their standards. CSAT guidelines are applicable to various phases of treatment. CSAT Opioid Accreditation Guidelines fall into 19 categories (see Figure 1). The standards related specifically to performance measurement include the following, in the category of Risk Management and Continuous Quality Improvement:

Legal issues

These standards relate to informed consent for all modes of treatment, including pharmacotherapy; reporting of all forms of abuse; adherence to federal regulations related to confidentiality; roles and responsibilities as described in rights statements; discharge procedures (including involuntary terminations); and the assurance that treatment staff have appropriate credentials to provide services.

Life safety issues

These standards include policies and procedures that address the correct dosing of medication and the reporting of untoward effects; a formal plan for the administration of medication in emergency situations; access to treatment staff 24 hours a day, 7 days a week; assurance that trained treatment staff can respond to basic medical emergencies; a formal disaster plan; and policies and procedures for safety and security.

Continuous quality improvement policies

Standards in this section relate to continuous training of staff; formal staff development plans; review and revision of program policies and procedures at least annually, including a mechanism to ensure input from clients and the community; periodic satisfaction surveys; adherence to universal precautions standards set forth by the Centers for Disease Control and Prevention (CDC); and measurement and monitoring of treatment processes and outcomes, such as:

- reducing or eliminating associated criminal activities

- reducing behaviors contributing to the spread of infectious diseases
- improving quality of life by restoration of physical and mental health, and functional status
- diversion control plans that demonstrate accountability to clients and the community (CSAT, 1999a).

Adverse events

This section includes standards on the monitoring and formal reporting of adverse events (e.g., medication errors, deaths, harm to family members due to ingesting client's medications, contraband at the program site, medication diversion, and harassment or abuse of patients). It also sets forth formal procedures for documenting, investigating, and reviewing the event; implementing corrective action; and evaluating the effectiveness of corrective action plans.

CARF Accreditation Standards

The original CARF OTP treatment program standards addressed philosophy and mission, organizational leadership, fiscal management, human resources, quality and appropriateness of services, outcomes management, structure and staffing, admission and assessment, medication management, and seclusion and restraint. The standards related specifically to performance measurement are given under Quality Improvement Systems, as follows:

Organizational planning

This standard addresses documentation of a formal, systematic quality program described in an annual organizational plan, with written goals and objectives, an annual management report, and needs assessment.

Quality and appropriateness of services

This standard states that organizations must have a systematic monitoring and evaluation process related to the ongoing measurement of quality, appropriateness, and utilization of services.

Outcomes management

This standard requires that formal outcomes management systems measure program effectiveness (quality of life, symptomatology, functional status, health status); efficiency (access, use appropriateness, cost); and customer satisfaction (The Rehabilitation Accreditation Commission [CARF], 1999).

Joint Commission Accreditation Standards

The Joint Commission developed standards specific to OTPs (JCAHO, 1999b) and incorporated subsequent revisions into its *Comprehensive Accreditation Manual for Behavioral Healthcare* (JCAHO, 1999a, 2000). Joint Commission accreditation standards address rights, responsibilities and ethics, continuum of care, physical examination/assessment, care, education, improvement of organizational performance, leadership, environment of care, human resources, and information management. The standards specifically related to performance measurement are as follows in the category of Improving Organizational Performance. Outcomes and processes including the following should be measured and monitored:

- reducing or eliminating use of illicit opioids and illicit drugs, and addressing the problematic use of licit drugs
- reducing or eliminating associated criminal activity
- reducing behaviors that contribute to the spread of infectious diseases
- improving quality of life by restoring physical and mental health and functional status (JCAHO, 1999b).

New Federal Rules and Regulations: Stakeholder Response

The new federal regulations mandate a “certification” system (administered by SAMHSA) based on accreditation, whereby a practitioner

...who intends to dispense opioid agonist medications in the treatment of opiate addiction must first obtain from SAMHSA a certification that the practitioner is qualified under the Health and Human Services Secretary’s standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from a private nonprofit entity, or from a state agency, that has been approved by SAMHSA to accredit OTPs” (USDHHS, 2001, p. 4076).

The regulations also require that the OTPs have formal QM/QI systems in place to continuously monitor and evaluate their services.

SAMHSA received nearly 200 comments in response to the proposed regulations dated July 22, 1999. Responses came from various stakeholders, including representatives from government, the healthcare industry, healthcare industry trade associations, academia, professional organizations, and advocacy organizations, as well as from health professionals and individual clients. A number of comments affirmed the effectiveness of accreditation-based systems in other behavioral health sectors and the positive effect of individualized care based upon evidence, best practice models, and clinical guidelines, including a method for measuring clinical outcomes of care. Accreditation also was seen as providing “the potential for mainstream medicine to embrace opioid treatment” (USDHHS, 2001, p. 4077). Some negative comments related to administrative burden. Comments from a group of OTPs related primarily to the indirect costs of preparing for, seeking, and following up with accreditation agency recommendations. These OTPs indicated that they had to hire consultants and additional staff, upgrade their information systems, develop policy manuals and make physical plant improvements. They also reported that the cost of implementing systems to support a new accreditation model that would comply with the new federal regulations was as high as \$50,000 per program.

SAMHSA and CSAT supported the development of this accreditation system by conducting an accreditation impact study and providing technical assistance to OTPs. CARF and the Joint Commission trained the staff of more than 170 OTPs. Of the almost 80 OTPs that Joint Commission or CARF members visited, approximately 90% of them achieved accreditation under the methadone accreditation standards. Only a few required a follow-up visit to achieve accreditation, and only one OTP failed to achieve accreditation under the new standards (USDHHS, 2001).

Mindful of the potential burden imposed by accreditation activities, SAMHSA is reducing the administrative burden by carefully reviewing private accrediting agencies’ standards and continuing to provide technical assistance to OTPs during the 3–5 year transition period. The DHHS estimates that the cost of this accreditation model will be approximately \$4 million to \$5 million per year (\$5,400 per OTP annually, \$39 per patient annually)

(USDHHS, 2001). The Secretary of Health and Human Services will allow states to use funds provided by SAMHSA under the Substance Abuse Prevention and Treatment block grants to fund accreditation-related implementation activities.

There are concerns that OTPs will be subjected to duplicative performance measurement requirements. This phenomenon is not unique to the methadone treatment industry. States will have to work with local programs to reduce duplication wherever possible. The DHHS has proposed that states apply for consideration as an accreditation body and accredit OTPs under the new federal regulations. In this way, the DHHS hopes that states “will consider OTP accreditation and federal certification requirements as sufficient to fulfill all or a substantial part of their licensing requirements” (USDHHS, 2001, p. 4079).

Indicator Measures and Performance Domains of Importance in Opioid Treatment

In applying the new federal regulations, OTPs will have to ensure that their comprehensive QM/QI systems include performance domains and measures that address key components. Key components or aspects of care for the OTP client population include intake processing/assessment, behavioral therapy and counseling, treatment planning, substance use monitoring, clinical and case management, pharmacotherapy, self-help/peer support groups, and continuing care (NIDA, 1999). These components are managed through agencies that provide various services (child care, vocational, mental health, medical, educational, sexually transmitted diseases [STDs], legal, financial, housing/transportation, and family counseling), depending upon the needs of each client and family.

The overall goal of drug treatment is to “help the individual stop using drugs and maintain a drug-free lifestyle, while achieving productive functioning in the family, at work, and in society” (NIDA, 1999). Hoffman and Moolchan (1994) have described goals of treatment within the context of a phases-of-treatment model for methadone maintenance. These goals include the following: (a) achieving functional stabilization, (b) committing to the process of treatment and rehabilitation, (c) achieving biopsychosocial balance and stabilization in the primary areas of adult functioning, and (d) achieving social integration while maintaining personal balance and physiological stability with ongoing methadone medication support, or tapering off methadone without relapsing to drug use or other self-destructive behavior, and reinforcing relapse-prevention and coping skills necessary to maintain a balanced and stable lifestyle.

OTPs will have to ensure that their comprehensive QM/QI systems include performance domains and measures that address key components.

Structure indicators

Structure indicators relate to those measures that assess “whether organizational resources and arrangements are in place to deliver healthcare, such as the number, type, and distribution of medical and ancillary personnel, equipment and facilities” (JCAHO, 1998, p. 14). Structure characterizes the system of care available to people with opioid addictions. These structure characteristics may include “individual practitioners, groups of practitioners, organizations and systems of care, geographic location, and accessibility of services” (National Roundtable on Health Care Quality, 1999, p. 7). Specifically, structure indicators in an OTP would include the number, type, and credentials of treatment staff; hours of operation; and access to emergency care. Program policies and procedures also are examples of structure indicators.

Process indicators

Process indicators relate to a “process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome” (JCAHO, 1998, p. 11). Process measures may include “interpersonal aspects of care, service, timeliness and convenience. Technical aspects of care include timeliness and accuracy of diagnosis, the appropriateness of therapy, complications and mishaps during treatments, and coordination of care across delivery settings, episodes of care, and professional disciplines” (National Roundtable, 1999, p. 8). All these process examples would be of interest to treatment staff and applicable to methadone treatment programs.

Outcomes

An outcome measure “indicates the result of the performance (or nonperformance) of a function or process” (JCAHO, 1998, p. 10). Health or clinical outcomes “include the traditional measures of survival (now commonly expressed as risk-adjusted mortality), unintended effects of treatment (e.g., infection), and the relief of symptoms” (National Roundtable, p. 8). Outcomes can be expressed either from the practitioner’s viewpoint or from that of the client and family.

Data obtained from the measurement of structure, process, and outcome indicators should be used to improve care and services to clients and their families. Comparison of these data with regional and national norms or benchmarks also should focus on identifying opportunities to improve care and service.

As defined by the Panel on Performance Measures and Data for Public Health Performance Partnership Grants (1999, p. 72), the domains of importance at a program level that are relevant to OTPs are as follows:

- treatment effectiveness
- treatment completion
- medical screening
- use during pregnancy
- HIV- and STD-related use
- overall use and consequences
- youth use and consequences
- other prevention activities
- access and special needs
- general and infrastructure issues.

Performance domains considered important as described in a MTQAS feasibility study include drug-using behavior, physical and mental health, social functioning, and treatment retention (Ducharme, Luckey, Ahn, Fulmer, & Graham, 1999).

As reported by Petillo (2000), performance measures important in a managed care program serving substance-abusing adults in Massachusetts included the following:

- utilization of substance abuse treatment

- effectiveness of care (as measured by client outcomes such as current alcohol and drug use, Addiction Severity Index scores, and symptomatic readmission to treatment)
- cost of public treatment (as measured by per-capita public treatment expenditures from agencies such as Medicaid, Medicare, Bureau of Substance Abuse Services, and Department of Mental Health)
- cost-effectiveness of care (including sensitivity analyses after inclusion of out-of-pocket costs and other societal costs)
- factors that increase the cost-effectiveness of care for chronic substance abuse clients from certain target groups (e.g., those with serious psychiatric comorbidity, intravenous drug users, pregnant women).

When discussing and determining performance domains of importance to their populations, OTP program staff can consult the Internet resources and connections listed in Figure 2.

Summary

It is hoped that moving oversight of OTPs from regulation by the FDA to accreditation by private accreditation agencies will improve the services provided to clients in OTPs. The monitoring and evaluation requirements as stipulated in the accreditation standards will increase OTPs' accountability and strengthen their performance measurement. Although OTPs may have concerns about increased administrative burden (based upon the effect of comprehensive quality programs in other healthcare sectors), they will see how effective performance measurement can be in improving services for clients and their families. Specific outcomes from a comprehensive quality program, as required by the new federal regulations, could include, but not be limited to, the following:

- moving from anecdotal to data-based decision making
- refining processes to increase efficiencies and reduce rework and waste
- strengthening the evaluation of the consumer's experience and perception of treatment
- instituting a quality culture that includes continuous improvement as a shared organizational value.

Because there is no national consensus on performance measures, OTPs will have to draw heavily from the research literature to accurately reflect and gain consensus on the domains of importance to their specific populations. Guidance in this article will assist those in their efforts.

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Administrative Organization and Responsibilities
Management of Facility and Clinical Environment
Risk Management and Continuous Quality Improvement
Professional Staff Credentials and Development
Patient Admission Criteria
Patient Medical and Psychosocial Assessment
Guidelines for Therapeutic Dosage
Treatment Planning, Evaluation of Patient Progress in
Treatment, and Continuous Clinical Assessment
Testing for Drug Use
Unsupervised Approved Use
Withdrawal and Discharge
Management of Concurrent Alcohol and Polysubstance Abuse
Concurrent Services
Special Considerations
Care of Women in Treatment
Patients' Rights
Record Keeping and Documentation
Community Relations and Education
Diversion Control

Figure 1.
CSAT Opioid Treatment Accreditation Guideline Categories

American Methadone Treatment Association
(www.americanmethadone.org)

Center for Mental Health Services
(www.mentalhealth.org/cmhs)

Center for Substance Abuse Treatment
(www.samhsa.gov/csat)

Joint Commission on Accreditation of Healthcare Organizations
(www.jcaho.org)

National Alliance for Methadone Advocates
(www.methadone.org)

National Institute on Drug Abuse
(www.nida.nih.gov)

The National Quality Forum/National Forum for Health Care
Quality Measurement and Reporting
(www.qualityforum.org)

The Rehabilitation Accreditation Commission (CARF)
(www.carf.org)

Substance Abuse and Mental Health Service Administration
(www.samhsa.gov)

Figure 2.
Internet Resources and Connections